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4 November, 2009

**Application No. 46132/08**  
**Z v. Poland**

Dear Sir,

Please find attached our written comments pursuant to Rule 44 § 2 and § 4 of the Rules of the Court.

These comments address the evidence-based medical standards concerning the treatment of pregnant women who have ulcerative colitis or similar diseases. These comments demonstrate that timely diagnostic testing and aggressive treatment of ulcerative colitis are likely to lead to the birth of a healthy baby and a healthy mother. Consequently, any perceived conflict between maternal treatment and fetal well-being is unfounded.

Sincerely,

Wendy Chavkin, MD, MPH  
Global Doctors for Choice

**IN THE EUROPEAN COURT OF HUMAN RIGHTS  
(APPLICATION No. 46132/08)  
Z. APPLICANT  
AND  
POLAND RESPONDENT  
WRITTEN COMMENTS SUBMITTED  
BY  
GLOBAL DOCTORS FOR CHOICE  
4 NOVEMBER, 2009**

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I. Introduction

Global Doctors for Choice submits these written comments pursuant to leave granted by the President of the Chamber in accordance with Rule 44 § 2 and § 4 of the Rules of the Court.

These comments address the evidence-based medical standards concerning the treatment of pregnant women who have ulcerative colitis. These comments demonstrate that timely diagnostic testing and aggressive treatment of ulcerative colitis are likely to lead to the birth of a healthy baby and a healthy mother. Consequently, any perceived conflict between maternal treatment and fetal well-being is unfounded.

II. Interest of Global Doctors for Choice

Global Doctors for Choice, housed at Columbia University’s Mailman School of Public Health in New York City, is an international group of doctors advocating for access to comprehensive and evidence based reproductive health services. It works to promote the effective application of medical and ethical standards to reproductive health and rights issues. In pursuit of its goals, it works together with other organizations in supporting cases and advocating before appropriate bodies. As such, Global Doctors for Choice has provided technical assistance to lawyers on medical and ethical standards on cases pending before international human rights bodies, including the European Court of Human Rights and the CEDAW Committee.

III. Standards for Treatment of Ulcerative Colitis in Pregnant Women

Ulcerative colitis (UC) is an inflammatory bowel disease (IBD) that causes chronic inflammation and ulcers in the lining of the rectum and large intestine. Although there is no cure available for UC, proper treatment can significantly reduce its symptoms and may lead to long-term remission.<sup>1</sup>

The peak age of onset for UC coincides with the peak age for conception and pregnancy. In pregnancies of women with UC, maternal and fetal mortality are exceptions, not the norm.<sup>2</sup> Pregnant women with inactive UC do not have an increased incidence of congenital abnormalities, spontaneous abortion, or stillbirth. They have the same risk of pregnancy-related complications compared with age-matched controls. However, pregnant women with active UC are at an increased risk of congenital abnormalities,

<sup>1</sup> Mayo Clinic, Ulcerative Colitis, <http://www.mayoclinic.com/health/ulcerative-colitis/DS00598>.

<sup>2</sup> In a study of 37 cases of UC in pregnant women from 1951 to 2004, the maternal and fetal mortality rates post-1987 were 0. Prior to 1987 they were 24% and 67% respectively. Eric J. Dozois et. al, *Maternal and Fetal Outcome After Colectomy for Fulminant Ulcerative Colitis During Pregnancy: Case Series and Literature Review*, 49 DISEASES OF THE COLON & RECTUM 64, 67 (2006).

spontaneous abortions, and stillbirth. Consequently, it is of the utmost importance to treat active UC properly and aggressively during pregnancy. To that end, women with UC should be monitored in a tertiary care facility that has experience with radiologic, endoscopic, and surgical procedures during pregnancy.<sup>3</sup>

When a pregnant patient who is not yet diagnosed with UC presents possible signs or symptoms, aggressive diagnostic testing to ascertain the condition is paramount, and a standard of care in Europe and around the world. Symptoms of UC include rectal pain and bleeding, bloody diarrhea, abdominal pain and cramps, fatigue, and weight loss.<sup>4</sup> Testing that should be provided at the first onset of potential symptoms are a sigmoidoscopy, with biopsy, and endoscopy. A sigmoidoscopy is an exam used to evaluate the lower part of the large intestine by inserting a thin, flexible tube with camera into the rectum. Tissue samples can be taken through the scope of the tube.<sup>5</sup> An endoscopy examines the upper part of the digestive system by inserting a flexible tube with camera through the mouth.<sup>6</sup> These procedures are safe during pregnancy.<sup>7</sup>

When symptoms deteriorate or are severe, more extensive testing is required- either colonoscopy and/or imaging studies (i.e. CT and/or MRI). While these procedures are more invasive than sigmoidoscopy and endoscopy, they are justified -as not performing them could expose both the pregnant woman and the fetus to harm. Moreover, they can be performed safely.

A colonoscopy is a more extensive sigmoidoscopy, allowing the physician to view and take samples of the entire inside of the rectum and large intestine.<sup>8</sup> Colonoscopies are generally considered safe during pregnancy.<sup>9</sup>

A CT<sup>10</sup> scan consists of multiple X-rays taken at different levels to assess the depth of an abnormality, such as an ulcer. CT scans expose patients to ionizing radiation, which could be harmful to the fetus by causing cell death or carcinogenesis. However, the risk of carcinogenesis is very small and does not warrant foregoing the procedure.<sup>11</sup> Cell death only becomes a risk with exposure to at least 20rad, which is approximately 6 times more than the dosage a fetus becomes exposed to during a CT scan of a woman's abdomen.<sup>12</sup>

3 Sonia Friedman, MD & Miguel D. Regueiro, MD, *Pregnancy and Nursing in Inflammatory Bowel Disease*, 31 GASTROENTEROLOGY CLINICS N. AM. 265, 265-66 (2002).

4 Mayo Clinic, Ulcerative Colitis: Symptoms, <http://www.mayoclinic.com/health/ulcerative-colitis/DS00598/DSECTION=symptoms>.

5 Mayo Clinic, Sigmoidoscopy, <http://www.mayoclinic.com/health/flexible-sigmoidoscopy/MY00622>.

6 Mayo Clinic, Endoscopy, <http://www.mayoclinic.com/health/endoscopy/MY00138>.

7 Sonia Friedman, MD & Miguel D. Regueiro, MD, *Pregnancy and Nursing in Inflammatory Bowel Disease*, 31 GASTROENTEROLOGY CLINICS N. AM. 265, 267 (2002).

8 Mayo Clinic, Colonoscopy, <http://www.mayoclinic.com/health/colonoscopy/MY00621>.

9 AM. SOC'Y FOR GASTROINTESTINAL ENDOSCOPY, *ASGE Guidelines: Guidelines for Endoscopy in Pregnant and Lactating Women*, 61 GASTROINTESTINAL ENDOSCOPY 357, 361 (2005).

10 CT: Computed Tomography.

11 AM. C. OBSTETRICIANS & GYNECOLOGISTS, Comm. on Obstetric Practice, Committee Opinion No. 299, *Guidelines for Diagnostic Imaging During Pregnancy* 2, 4 (Sept. 2004).

12 The dose a fetus becomes exposed to during a CT of the pregnant woman's abdomen is 3.5rad. AM. C. OBSTETRICIANS & GYNECOLOGISTS, Comm. on Obstetric Practice, Committee Opinion No. 299, *Guidelines for Diagnostic Imaging During Pregnancy* 2, 4 (Sept. 2004).

Hence, use of a CT scan to diagnose UC in a pregnant woman is not associated with an increase in fetal abnormalities or pregnancy loss. The procedure can therefore be performed during pregnancy when medically indicated, and is the standard of care in Europe and around the world.<sup>13</sup> With MRI,<sup>14</sup> there is no exposure to ionizing radiation. The technique is not associated with any known adverse fetal effects, and can safely be used on women during pregnancy for diagnostic testing.<sup>15</sup> Thus, the medical evidence does not support that concern for fetal well-being provides a sound basis to abstain from aggressive diagnostic testing when UC is suspected in a pregnant woman.

Extensive testing leads to an accurate diagnosis of UC, which is necessary to be able to provide adequate, aggressive, and timely treatment. Once the extent, location, and severity of the ulcerative colitis have been established, medications that are safe in pregnancy, including anti-inflammatory drugs, antibiotics, and steroids, can be used to treat the disease very effectively. The danger to the fetus from active UC is greater than the danger from medications used to treat the disease.<sup>16</sup>

With appropriate treatment, bowel perforation, extensive abscess formation, and sepsis, which may lead to death, as it did in the case of Z, can be prevented. Furthermore, timely and aggressive treatment is likely to result not only in the well-being of the pregnant woman, but precisely by tending to the pregnant woman's health, in the well-being of the fetus as well.

#### IV. Conclusion

Global Doctors for Choice respectfully submits that, in its opinion, the medical evidence requires aggressive and timely treatment of women with active UC during pregnancy. Such treatment includes proper, and if necessary, extensive, diagnostic testing, which can be performed safely, without risk of any known harmful effects to the fetus. When UC is accurately diagnosed, medications that are safe in pregnancy can and should be used to control the disease. Timely diagnostic testing and aggressive treatment of UC are likely to lead to the birth of a healthy baby and a healthy mother. Failure to provide such care, could lead to fetal death. Such treatment is the standard of care in Europe and around the world. Active UC places both the pregnant woman and fetus at greater risk than proper treatment of the disease during pregnancy. Consequently, any suggestion of a conflict between maternal treatment and fetal well-being in cases of UC is unfounded. Global Doctors for Choice respectfully trusts that its opinion on standards of care for treatment of pregnant women with ulcerative colitis, based on medical evidence, will be of assistance to the Court in its deliberations.

Respectfully submitted

<sup>13</sup> The doses a fetus becomes exposed to during a CT of the pregnant woman's abdomen is 3.5rad. AM. C. OBSTETRICIANS & GYNECOLOGISTS, Comm. on Obstetric Practice, Committee Opinion No 299, *Guidelines for Diagnostic Imaging During Pregnancy 2* (Sept. 2004).

<sup>14</sup> MRI: Magnetic Resonance Imaging

<sup>15</sup> AM. C. OBSTETRICIANS & GYNECOLOGISTS, Comm. on Obstetric Practice, Committee Opinion No 299, *Guidelines for Diagnostic Imaging During Pregnancy 2* (Sept. 2004).

<sup>16</sup> Sonia Friedman, MD & Miguel D. Regueiro, MD, *Pregnancy and Nursing in Inflammatory Bowel Disease*, 31 *GASTROENTEROLOGY CLINICS N. AM.* 265, 265 (2002).